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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,189	11/27/2000	Gerhard Benner	Beiersdorf 670	5654

7590 06/18/2002
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New York, NY 10017

EXAMINER

HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/18/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/723,189

Applicant(s)

BENNER ET AL.

Examiner

Mina Haghighatian

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-- The MAILING DATE of this communication appears n the c ver sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2002 .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____ .

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: A brief description of drawings is required in the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The remarks filed 04/03/02 indicates that the shea butter used in the composition of the present application is in its solid form only. It is unclear as to how an oil-in-water emulsion is prepared without the use of an oil and water. Claim 1 is requiring an emulsifier, optional dispersible or soluble substances and shea butter.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ascione et al (5,858,334) in view of Gohla et al (5,750,124).

Ascione teaches stable and homogenous, topically applicable cosmetic compositions well suited for artificially tanning human skin, comprise a storage-stable, ultrafine oil-in-water emulsion (abstract). The ultrafine oil-in-water emulsions are themselves preferably obtained via the so called "phase inversion" technique (col. 1, lines 65-66). The oil-in-water emulsions may contain oils such as mineral oils, vegetable oils such as karite butter (also known as shea butter) or synthetic oils in the fatty phase (col. 2, lines 41-64).

Ascione also discloses the preferred emulsifiers for the said emulsions, which are in the concentration range from 0.5 to 20% by weight of the total composition (col.3, line 47 to col. 4, line 23). Ascione lacks specific teachings on the properties of emulsifiers.

Gohla teaches multiple emulsions comprising at least one emulsifier whose lipophilicity increases with increasing temperature and hydrophilicity of which increases with decreasing temperature, the emulsifiers changing from an HLB value <10 to an HLB value of >10 in the temperature range of 40-90 degrees centigrade, the HLB value of the emulsifier or emulsifiers at room temperature being between 11 and 18, the emulsifier not being completely soluble in the oily phase; also optionally further auxiliaries and/or additives to stabilize the multiple emulsion droplets; and other additives and/or active compounds customary in cosmetics or medical preparations, (see abstract and col. 11, lines 9-67).

Gohla also discloses oil phase to be formed from oils such as mineral oil and vegetable oils such as wheatgerm oil, grapeseed oil etc (see examples 1-11). Process of preparing oil-in-water emulsions are described in column 12, lines 28-39.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the composition of Ascione, an emulsion containing karite butter, by using the teachings of Gohla on the emulsions containing emulsifiers with such specific properties, because of the expectancy of producing composition systems which are stable microscopically over relatively long storage times or in a wide temperature range or towards extreme variations in temperature.

Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ascione et al and Gohla et al as applied to claims 1-3 and 6-11 above, and further in view of Muller et al (4,719,239).

Ascione and Gohla's teachings, discussed above, lack specific teachings on microemulsions or macroemulsions.

Muller teaches pharmaceutical multicomponent systems and method of preparing them. He teaches that macroemulsions form at room temperature and microemulsions form at higher temperatures, and that traditional macroemulsions and microemulsions were lacking stability and therefore were not suitable carriers. Muller then, discloses that the nature and concentration of the coemulsifiers of the surfactant

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and cosurfactant determine both the scope of the thermodynamic, stable, single-phase range and also the viscosity of the system and the temperature range in which there is thermodynamic stability.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the composition of the combined references of an emulsion containing karite butter and emulsifiers with specific properties, by using the teachings of Muller on macroemulsions and microemulsions systems, because of the expectancy to produce an emulsion system which is both stable and convertible, and would ultimately perform better as a cosmetic and/or pharmaceutical carrier.

Claims 1-3 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gohla et al (5,750,124) in view of applicant's admission.

Gohla, discussed above, lacks specific disclosure of shea butter.

Applicant admits, in the specification, page 10, lines 13-16, that shea fat and shea fat fractions have been known in skincare for a long time for their care and protecting properties. The action of these fatty substances is attributed to an influencing of biochemical inflammation processes since the UV absorption in the UVA and UVB region is only weakly defined. Applicant also admits that shea butter is commercially available (page 9).

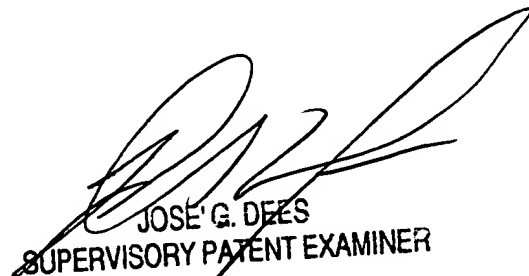
It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have prepared the emulsion of Gohla, and substituted shea butter for vegetable oils because of known properties and benefits of shea butter in care and protection of skin, and with the reasonable expectation of obtaining a skincare formulation which has the combined properties of the emulsifiers and shea butter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghghatian whose telephone number is 703-308-6330. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghghatian
June 14, 2002


JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616